Optum Rx®

Sotyktu™ (deucravacitinib) – New drug approval

- On September 9, 2022, Bristol Myers Squibb announced the FDA approval of Sotyktu (deucravacitinib), for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
    - Sotyktu is not recommended for use in combination with other potent immunosuppressants.
- Psoriasis affects approximately 7.5 million people in the U.S. Nearly one-quarter of people with psoriasis have cases that are considered moderate-to-severe and up to 90% of patients with psoriasis have psoriasis vulgaris, or plaque psoriasis, which is characterized by distinct round or oval plaques typically covered by silvery-white scales.
- Sotyktu is a first-in-class selective, allosteric inhibitor of tyrosine kinase 2 (TYK2). TYK2 is a member of the Janus kinase (JAK) family.
- The efficacy of Sotyktu was established in two randomized, double-blind, placebo- and active-controlled clinical studies (PSO-1 and PSO-2) in 1,684 patients 18 years of age and older with moderate-to-severe plaque psoriasis. Patients were randomized to either Sotyktu, placebo, or Otezla® (apremilast). Both studies assessed the responses at week 16 compared to placebo for the two co-primary endpoints: proportion of patients who achieved a static Physician's Global Assessment (sPGA) score of 0 (clear) or 1 (almost clear) with at least a 2-grade improvement from baseline; and the proportion of patients who achieved at least a 75% improvement in Psoriasis Area and Severity Index (PASI) scores from baseline (PASI 75). Secondary endpoints included comparisons between Sotyktu and Otezla.
    - The tables below present the efficacy results of PSO-1 and PSO-2.

PSO-1: Efficacy results

Endpoint	Sotyktu	Placebo	Otezla	Difference, % (95% CI)	
				Difference from placebo	Difference from Otezla
sPGA response of 0/1 (clear or almost clear)					
Week 16	54%	7%	32%	47 (40, 53)	22 (13, 30)
Week 24	59%	--	31%	--	27 (19, 36)
PASI 75 response					
Week 16	58%	13%	35%	46 (39, 53)	23 (14, 32)
Week 24	69%	--	38%	--	31 (22, 40)

PSO-2: Efficacy results

Endpoint	Sotyktu	Placebo	Otezla	Difference, % (95% CI)	
				Difference from placebo	Difference from Otezla
sPGA response of 0/1 (clear or almost clear)					
Week 16	50%	9%	34%	41 (35, 46)	16 (9, 23)
Week 24	49%	--	30%	--	20 (13, 27)
PASI 75 response					
Week 16	53%	9%	40%	44 (38, 49)	13 (6, 21)
Week 24	58%	--	38%	--	20 (13, 27)

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- Warnings and precautions for Sotyktu include hypersensitivity, infections, tuberculosis, malignancy including lymphomas, rhabdomyolysis and elevated creatine phosphokinase, laboratory abnormalities, immunizations, and potential risks related to JAK inhibition.
- The most common adverse reactions (≥ 1%) with Sotyktu use were upper respiratory infections, increased blood creatine phosphokinase, herpes simplex, mouth ulcers, folliculitis, and acne.
- The recommended dosage of Sotyktu is 6 mg taken orally once daily, with or without food.
- Sotyktu will be priced at approximately $75,000 per year.
- Bristol Myers Squibb plans to launch Sotyktu in September 2022. Sotyktu will be available as a 6 mg tablet.

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